

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2479

To amend title XVIII of the Social Security Act to modify the designation of accreditation organizations for prosthetic devices and orthotics and prosthetics, to apply accreditation and licensure requirements to such devices and items for purposes of payment under the Medicare Program, and to modify the payment rules for such devices and items under such program to account for practitioner qualifications and complexity of care.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2009

Ms. BERKLEY introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to modify the designation of accreditation organizations for prosthetic devices and orthotics and prosthetics, to apply accreditation and licensure requirements to such devices and items for purposes of payment under the Medicare Program, and to modify the payment rules for such devices and items under such program to account for practitioner qualifications and complexity of care.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare Orthotics and  
3 Prosthetics Improvement Act of 2009”.

4 **SEC. 2. MODIFICATION OF REQUIREMENTS APPLICABLE**  
5 **UNDER MEDICARE TO DESIGNATION OF AC-**  
6 **CREDITATION ORGANIZATIONS FOR SUP-**  
7 **PLIERS OF PROSTHETIC DEVICES AND**  
8 **ORTHOTICS AND PROSTHETICS.**

9 (a) IN GENERAL.—Section 1834(a)(20)(B) of the So-  
10 cial Security Act (42 U.S.C. 1395m(a)(20)(B)) is amend-  
11 ed—

12 (1) by striking “Not later than” and inserting  
13 “(i) IN GENERAL.—Subject to clause (ii), not later  
14 than” with the same indentation as the clause added  
15 by paragraph (2); and

16 (2) by adding at the end the following new  
17 clause:

18 “(ii) SPECIAL REQUIREMENTS FOR  
19 ACCREDITATION OF PROSTHETIC DEVICES  
20 AND ORTHOTICS AND PROSTHETICS.—For  
21 purposes of applying quality standards  
22 under subparagraph (A) for suppliers of  
23 items and services described in subpara-  
24 graph (D)(ii), the Secretary shall designate  
25 and approve an independent accreditation  
26 organization under clause (i) only if such

1 organization is a Board or program de-  
 2 scribed in subsection (h)(1)(F)(iv). Not  
 3 later than January 1, 2010, the Secretary  
 4 shall ensure that at least one independent  
 5 accreditation organization is designated  
 6 and approved in accordance with this  
 7 clause.”.

8 (b) EFFECTIVE DATE.—An organization must satisfy  
 9 the requirement of section 1834(a)(20)(B)(ii), as added  
 10 by subsection (a)(2), not later than January 1, 2010, re-  
 11 gardless of whether such organization is designated or ap-  
 12 proved as an independent accreditation organization be-  
 13 fore, on, or after the date of the enactment of this Act.

14 **SEC. 3. APPLICATION OF EXISTING ACCREDITATION AND**  
 15 **LICENSURE REQUIREMENTS FOR CERTAIN**  
 16 **PROSTHETICS AND CUSTOM-FABRICATED**  
 17 **ORTHOTICS TO PROSTHETIC DEVICES AND**  
 18 **ORTHOTICS AND PROSTHETICS.**

19 (a) IN GENERAL.—Section 1834(h)(1)(F) of the So-  
 20 cial Security Act (42 U.S.C. 1395m(h)(1)(F)) is amend-  
 21 ed—

22 (1) in the heading, by striking “SPECIAL PAY-  
 23 MENT RULES FOR CERTAIN PROSTHETICS AND CUS-  
 24 TOM-FABRICATED ORTHOTICS” and inserting “PAY-  
 25 MENT RULES”;

1           (2) in clause (i), by striking “an item of cus-  
2           tom-fabricated orthotics described in clause (ii) or  
3           for an item of prosthetics unless such item is” and  
4           inserting “a prosthetic device or an item of orthotics  
5           or prosthetics, including an item of custom-fab-  
6           ricated orthotics described in clause (ii), unless such  
7           device or item, respectively, is”;

8           (3) in clause (ii)(II), by striking “a list of items  
9           to which this subparagraph applies” and inserting  
10          “a list of items for purposes of clause (i)”;

11          (4) in clause (iii)(III), by striking “to provide  
12          or manage the provision of prosthetics and custom-  
13          designed or -fabricated orthotics” and inserting “to  
14          provide or manage the provision of prosthetics and  
15          orthotics (and custom-designed or -fabricated  
16          orthotics, in the case of an item described in clause  
17          (ii))”.

18          (b) EFFECTIVE DATE.—The amendments made by  
19          subsection (a) shall apply to devices and items furnished  
20          on or after January 1, 2010.

1 **SEC. 4. MEDICARE PAYMENT RULES FOR PROSTHETIC DE-**  
2 **VICES AND ORTHOTICS AND PROSTHETICS**  
3 **TO ACCOUNT FOR PRACTITIONER QUALI-**  
4 **FICATIONS AND COMPLEXITY OF CARE.**

5 Section 1834(h) of the Social Security Act (42 U.S.C.  
6 1395m(h)) is amended—

7 (1) in paragraph (1)(F)(iii), by striking “other  
8 individual who” and inserting “other individual who,  
9 with respect to a category of orthotics and pros-  
10 thetics care described in clause (i), (ii), (iii), (iv), or  
11 (v) of paragraph (5)(C) furnished on or after Janu-  
12 ary 1, 2010, satisfies all applicable criteria of the  
13 provider qualification designation for such category  
14 described in the respective clause, and who”;

15 (2) in paragraph (1)(F)(iv), by inserting before  
16 the period the following: “and, with respect to a cat-  
17 egory of orthotics and prosthetics care described in  
18 clause (i), (ii), (iii), (iv), or (v) of paragraph (5)(C)  
19 and furnished on or after January 1, 2010, satisfies  
20 all applicable criteria of the provider qualification  
21 designation for such category described in the re-  
22 spective clause”; and

23 (3) by adding at the end the following new  
24 paragraph:

1           “(5) PAYMENT RULES TO ACCOUNT FOR PRAC-  
2           TITIONER QUALIFICATIONS AND COMPLEXITY OF  
3           CARE.—

4           “(A) IN GENERAL.—In applying clauses  
5           (iii) and (iv) of paragraph (1)(F) for purposes  
6           of determining whether payment may be made  
7           under this subsection for prosthetic devices and  
8           orthotics and prosthetics furnished on or after  
9           January 1, 2010, the Secretary shall take into  
10          account the complexity of the respective item  
11          and the qualifications of the individual or entity  
12          furnishing and fabricating such respective item  
13          in accordance with this paragraph.

14          “(B) ASSIGNMENT OF BILLING CODES.—  
15          For purposes of subparagraph (A), the Sec-  
16          retary shall utilize and incorporate the set of L-  
17          codes listed, as of the date of the enactment of  
18          this paragraph, in the ‘2008 Orthotics and  
19          Prosthetics Tripartite Document’, a multi-orga-  
20          nization compilation of HCPCS codes, to assign  
21          specific billing codes to the category of orthotics  
22          and prosthetics care described in each of  
23          clauses (i) through (v) of subparagraph (C)  
24          using the provider qualification designation for  
25          each HCPCS code as stated in such document.

1 In the case that such document is updated or  
2 reissued, the previous sentence shall be applied  
3 with respect to the most recent update or  
4 reissuance of such document.

5 “(C) CATEGORIES OF ORTHOTICS AND  
6 PROSTHETICS CARE DESCRIBED.—

7 “(i) CUSTOM FABRICATED PROS-  
8 THETICS CATEGORY.—The category of  
9 orthotics and prosthetics care described in  
10 this clause is a category for custom fab-  
11 ricated prosthetics devices that are made  
12 from detailed measurements, images, or  
13 models in accordance with a prescription  
14 and that can only be utilized by a specific  
15 intended patient. The provider qualifica-  
16 tion designation for the category shall re-  
17 flect the following:

18 “(I) The category of care involves  
19 the highest level of complexity with  
20 substantial clinical risk.

21 “(II) The category of care re-  
22 quires a practitioner who is educated  
23 and trained with a course of study  
24 specific to and is credentialed, cer-  
25 tified, or licensed in prosthetics to en-

1                   sure the comprehensive provision of  
2                   prosthetic care. Such care shall be  
3                   based on sound clinical judgment and  
4                   technical expertise based on the prac-  
5                   titioner’s education and clinical train-  
6                   ing, in order to allow the practitioner  
7                   to determine the device parameters  
8                   and design, fabrication process, and  
9                   functional purpose specific to the  
10                  needs of the patient to maximize opti-  
11                  mal clinical outcomes.

12                  “(ii)           CUSTOM           FABRICATED  
13                  ORTHOTICS CATEGORY.—The category of  
14                  orthotics and prosthetics care described in  
15                  this clause is a category for custom fab-  
16                  ricated orthotics devices that are made  
17                  from detailed measurements, images, or  
18                  models in accordance with a prescription  
19                  and that can only be utilized by a specific  
20                  intended patient. The provider qualifica-  
21                  tion designation for the category shall re-  
22                  flect the following:

23                                  “(I) The category of care involves  
24                                  the highest level of complexity with  
25                                  substantial clinical risk.



1                   “(II) The category of care re-  
2                   quires a practitioner who is educated  
3                   and trained with a course of study  
4                   specific to orthotics and is  
5                   credentialed, certified, or licensed in  
6                   orthotics to ensure the appropriate  
7                   provision of orthotic care. Such care  
8                   shall be based on sound clinical judg-  
9                   ment and technical expertise based on  
10                  the practitioner’s education and clin-  
11                  ical training, in order to allow the  
12                  practitioner to determine the device  
13                  parameters and design, fabrication  
14                  process, and functional purpose spe-  
15                  cific to the needs of the patient to  
16                  maximize optimal clinical outcomes.

17                  “(iii) CUSTOM FITTED HIGH.—The  
18                  category of orthotics and prosthetics care  
19                  described in this clause is a category for  
20                  prefabricated orthotics devices that are  
21                  manufactured with no specific patient in  
22                  mind, but that are appropriately sized,  
23                  adapted, modified, and configured (with  
24                  the required tools and equipment) to a spe-  
25                  cific patient in accordance with a prescrip-

1 tion. The provider qualification designation  
2 for the category shall reflect the following:

3 “(I) The category of care involves  
4 moderate to high complexity with sub-  
5 stantial clinical risk.

6 “(II) The category of care re-  
7 quires a practitioner who is educated  
8 and trained with a course of study  
9 specific to orthotics and is  
10 credentialed, certified, or licensed in  
11 orthotics to ensure the appropriate  
12 provision of orthotic care. Such care  
13 shall be based on sound clinical judg-  
14 ment and technical expertise based on  
15 the practitioner’s education and clin-  
16 ical training, in order to allow the  
17 practitioner to determine the appro-  
18 priate device relative to the diagnosis  
19 and specific to the needs of the pa-  
20 tient to maximize optimal clinical out-  
21 comes.

22 “(iv) CUSTOM FITTED LOW.—The cat-  
23 egory of orthotics and prosthetics care de-  
24 scribed in this clause is a category for pre-  
25 fabricated orthotics devices that are manu-

1 factured with no specific patient in mind,  
2 but that are appropriately sized and ad-  
3 justed to a specific patient in accordance  
4 with a prescription. The provider qualifica-  
5 tion designation for the category shall re-  
6 flect the following:

7 “(I) The category of care involves  
8 a low level of complexity and low clin-  
9 ical risk.

10 “(II) The category of care re-  
11 quires a supplier that is credentialed,  
12 certified, or licensed within a limited  
13 scope of practice to ensure appro-  
14 priate provision of orthotic care. The  
15 supplier’s education and training shall  
16 insure that basic clinical knowledge  
17 and technical expertise is available to  
18 confirm successful fit and device com-  
19 pliance with the prescription.

20 “(v) OFF-THE-SHELF.—The category  
21 of orthotics and prosthetics care described  
22 in this clause is a category for prefab-  
23 ricated devices that require minimal self  
24 adjustment for appropriate use. The pro-  
25 vider qualification designation for the cat-

1           egory shall reflect that such devices do not  
2           require expertise in trimming, bending,  
3           molding, assembling, or customizing to fit  
4           the patient and that no formal  
5           credentialing, clinical education, or tech-  
6           nical training is required to dispense such  
7           devices.

8           “(D) CONSULTATION.—In modifying the  
9           payment basis, the Secretary shall consult with  
10          appropriate experts in orthotics and prosthetics,  
11          including practitioners that furnish devices and  
12          items within the categories of prosthetics and  
13          orthotics care described in subparagraph (C).

14          “(E) BUDGET NEUTRALITY.—This para-  
15          graph shall be applied in a manner to result in  
16          the same aggregate amount of expenditures for  
17          prosthetic devices and orthotics and prosthetics  
18          under this section for a year as would be made  
19          if this paragraph did not apply, as estimated by  
20          the Secretary.”.

21 **SEC. 5. REPORTS.**

22          (a) REPORT ON ENFORCING NEW LICENSING AND  
23          ACCREDITATION REQUIREMENTS.—Not later than 18  
24          months after the date of the enactment of this Act, the  
25          Secretary of Health and Human Services shall submit to

1 Congress a report on the steps taken by the Department  
2 of Health and Human Services to ensure that the State  
3 licensure and accreditation requirements under section  
4 1834(h)(1)(F) of the Social Security Act, as amended by  
5 section 3, are enforced. Such report shall include a deter-  
6 mination of the extent to which payments for prosthetic  
7 devices and orthotics and prosthetics under the Medicare  
8 program under title XVIII of such Act are made only to  
9 those providers of services and suppliers that meet the rel-  
10 evant accreditation and licensure requirements under such  
11 section, as well as a determination of whether additional  
12 steps are needed.

13 (b) REPORT ON FRAUD AND ABUSE.—Not later than  
14 30 months after the date of the enactment of this Act,  
15 the Secretary of Health and Human Services shall submit  
16 to Congress a report on the effect of the requirements  
17 under subsection (a)(20)(B)(ii) of section 1834 of the So-  
18 cial Security Act (42 U.S.C. 1395m), as added by section  
19 2, and subsection (h)(1)(F) of such section, as amended  
20 by section 3, on the occurrence of fraud and abuse under  
21 the Medicare program under title XVIII of such Act, with  
22 respect to prosthetic devices and orthotics and prosthetics  
23 for which payment is made under such program.

1 **SEC. 6. RULES OF CONSTRUCTION.**

2 (a) SCOPE OF PRACTICE.—Nothing in this Act shall  
3 be construed as superceding or otherwise affecting a provi-  
4 sion of State law insofar as such law relates to the scope  
5 of practice for occupational therapists, physical therapists,  
6 or both.

7 (b) NO EFFECT ON OTHER SERVICES.—Nothing in  
8 this Act shall be construed as modifying the ability, in ex-  
9 istence as of the date of the enactment of this Act, of a  
10 physical therapist or occupational therapist to provide  
11 services for which payment may be made under title XVIII  
12 of the Social Security Act if such services are completely  
13 distinct from the fabrication and sale of prosthetic devices  
14 and orthotics and prosthetics described in section  
15 1834(h)(4) of the Social Security Act (42 U.S.C.  
16 1395m(h)(4)), such as assisting in adapting or using such  
17 devices, gate training, or other equivalent services.

○